REMARKS

Applicants note with appreciation the detail and thoroughness of the Office Action of 17 April 2006. This amendment is submitted to be fully responsive thereto. By way of this amendment, claims 8, 13, 16-18, 20, 23-24 and 30 have been amended. Claims 25, 28 and 29 have been canceled.

Currently, claims 8-24, 26-27 and 30 stand rejected under 35 U.S.C. §112, second paragraph, principally as to the indefiniteness of A-R_1, as well as other aspects. Claims 8-19 and 30 also stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement. The rejection of claim 25 under 35 U.S.C. §112, first paragraph, as constituting new matter is moot in light of the cancellation of this claim. The rejection of claims 28-29 under 35 U.S.C. §101 is moot in light of the cancellation of these claims.

Remarks Directed to Rejection of Claims 8-24, 26-27 and 30 under 35 U.S.C. §112, Second Paragraph

As to the rejection to claims 8-24, 26-27 and 30 on the clarity of formula structure of A-R_1, claim 8 has been amended to recite with clarity the structure of A-R_1. In addition, Applicants submit that the conjunction "or" is appropriate and it is located in the original claim (see "....O, N, or S; or a bile acid...").

As to the rejection to claims 8-19 and 30, claim 8 is amended to read "Q is a sulfur, nitrogen, or oxygen". Support for this amendment is found in the specification at page 9, line 23 to page 10, line 1. As such, it is submitted that no new matter has been added to the application by way of this amendment.

As to the rejection to claim 13 on the definition of a gene, claim 8 is amended to read "nucleic acid delivery" to replace "gene delivery". Support for this amendment is found in the

specification at page 1, lines 8-10. As such, it is submitted that no new matter has been added to the application by way of this amendment.

As to the rejection to claims 21 and 22, claim 20 is amended to read "R_1 is a cholesterol derivative...where A is a hydrophilic moiety...". With this amendment, A and R_1 are separate yet connected moieties. Support for this amendment is found in the specification at page 20, lines 17-23. As such, it is submitted that no new matter has been added to the application by way of this amendment.

As to the rejection to claim 23 on the antecedent basis for "said A derivative", the claim is amended.

As to the rejection to claim 24 on the antecedent basis for "said Q derivative", the claim is amended.

The rejection to claims 28 and 29 is moot as these claims have been canceled.

As to the rejection to claim 30, the claim has been amended to provide proper antecedent basis. Withdrawal of the rejections to claims 8-24, 26-27 and 30 under 35 U.S.C. §112, second paragraph is requested.

Remarks Directed to Rejection of Claim 25 under
35 U.S.C. §112, First Paragraph, as New Matter

As to the rejection to claim 25 as constituting new matter, the Examiner's attention is directed to Y being chosen to adopt a peptide sequence which lacks "charged" residues (page 10, line 17). This sequence is so designed as to avoid ionic reactions to Z which is a polyionic peptide (page 10, lines 2 and 18). Nevertheless, this claim has been canceled.

Remarks Directed to Rejection of Claims 8-19 and 28-30 under 35 U.S.C. §112, First Paragraph, as Failing to Comply with the Enablement Requirement

With the current amendment, claims 8-19 are drawn to a method of delivering therapeutic nucleic acids to a subject so that *in vivo* degradation of such exogenous nucleic acid is limited. The currently amended claims along with working examples disclosed in the specification would enable one skilled in the art to make and use the claimed invention. Since the newly amended claims are no longer drawn to methods of "treating any disease condition" but rather to the method of nucleic acid delivery, it is submitted that the Examiner's enablement rejection based on the former is no longer appropriate.

In the claimed invention, a method is provided for the packaging of a nucleic acid with a chelating agent having a coordinating moiety linked to a central hydrophobic moiety that terminates in a hydrophilic moiety (page 2, lines 21-23). In a preferred embodiment, a nucleic acid conjugating agent contains a bile acid linked with a polycationic peptide (page 3, line 5-7). Examples 1 through 5 (page 20, line 10 to page 23, line 12) in the specification illustrate a working model of how this "packaging" is practically accomplished. A critical issue addressed by the current invention is to reduce and limit gastric degradation of exogenous nucleic acids by this "packaging" technique. Examples 6-8 (page 23, line 16 to page 25, line 20) demonstrate exactly this limited gastric degradation of exogenous nucleic acids. Examples 10-12 (page 26, line 1 to page 27, line 20) show the acceptable absorption of this packaged nucleic acid complex by gastrointestinal cells.

In addition, Applicants disclose dosage and administration terms of introducing nucleic acid compounds into a human body (page 9, line 1-8). Applicants note the historical difficulties associated with injecting nude nucleic acids via oral or intestinal routes (page 1, line 15 to page 2, line 4), yet the very aim of the present invention is to increase the efficiency of the delivery of

such therapeutic nucleic acid complex by a protection mechanism employing the use of bile salt conjugates. The current invention specifically focuses on the composition and method preventing exogenous therapeutic nucleic acid from intestinal degradation.

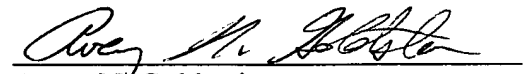
As to the rejections directed to the specification on pages 4-6 as lack of enablement under 35 U.S.C. §112, first paragraph, Applicants submit that it is the deficiency of the 49 listed proteins or body parts that constitutes the targeted utility of the present invention. The corresponding portion of the specification has been amended accordingly.

In light of the above remarks, Applicants respectfully request the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

Summary

Claims 8-24, 26-27 and 30 are the pending claims in this application. Each claim is believed to be in proper form and directed to allowable and patentable subject matter. Reconsideration and allowance of the claims is requested. The Examiner is kindly requested to contact the undersigned attorney in charge of this application in the event that issues remain after consideration of this amendment.

Respectfully submitted,



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